[redacted] [redacted]

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
SAH
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/388,567	01/12/95	KELLY G	2714

12M1/0910
DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA PA 19103-2307

EXAMINER	
WILSON, J	
ART UNIT	PAPER NUMBER
1211	8

DATE MAILED: 09/10/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	

ART UNIT	PAPER NUMBER
1625	8

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on April 30, 1996.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 (Three) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON _____ -WING PAGES --

The requirement for restriction as set forth in the Office Action dated April 30, 1996 has been withdrawn. The instant application, 08/338,567 has been filed under 35 USC §371 and the product and process for using same are seen to have unity of invention.

This application does not contain an Abstract of the Disclosure as required by 37 C.F.R. § 1.72(b). An Abstract on a separate sheet is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make and or use the invention (i.e. failing to provide an enabling disclosure).

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). The essence of the invention, must be described in such details, including proportions and techniques where necessary,

as to enable those persons skilled in the art to make and utilize the invention. Presently, there is not seen in the instant written description in full, clear and exact terms, adequate disclosures which teach how to determine what the specific therapeutically and pharmaceutically effective amounts of the active agents contain a glycoside of Genistein, Daidzein, Biochanin A or Formononectin. The disclosure appears to set forth only one combination of multiple phyto-oestrogen compounds in composition form, said combination being exemplified in Example 4. It is not seen where the "health" of a human is significantly improved by the administration of the composition instantly claimed. The reduction of cholesterol levels in a human has not been equated in this art with "improving health". Applicant's disclosure appears to support the lowering of cholesterol levels, however, the instant specification does not provide information which would teach that lowering the cholesterol level in a human with acceptably low cholesterol levels improves the health of said human appreciably. There is also not seen support in the specification for treating healthy humans. All humans, male and female, are at risk or "may develop" breast cancer and benign breast disease. The treatment of specific situations relating to Pre-Menstrual Syndrome (PMS) and (undisclosed) symptoms associated with menopause or a combination of said conditions (e.g. breast cancer and symptoms associated with menopause) as such relate to women are not seen to be adequately supported by the

instant disclosure.

The instant specification invites the skilled artisan to experiment. The factors which should be considered in determining undue experimentation are set forth in Ex parte Forman 230 USPQ 546. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art and the
7) breath of the claims.
8) level of skill in the art

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed to determine the specific identity and ratio of the combination of phyto-oestrogen compounds applicant intends to utilize in the treatment of certain conditions in humans which include:

1) Breast Cancer,
2) Benign Breast Disease,
3) Pre-Menstrual Syndrome,
4) Symptoms associated with Menopause
5) Combinations of 1-4 cited supra,

would indeed require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be provided. The absence of specific disclosures or the correlation of data to support applicant's assertions , invites the skilled artisan to engage in undue experimentation. The

quantity of experimentation needed to determine the specific identity and the amounts of phyto-oestrogen active agents needed to practice the instant methods as they relate to conditions cited supra in a patient and the time table necessary to achieve efficacious administration of said active agents, would require a great deal of experimentation which would impose an undue burden upon the skilled artisan in this field. Although applicant alleges that their invention is enabled for the beneficial administration of multiple phyto-oestrogen compounds, the instant disclosure appears to be limited to daidzein and genistein utilized in a ratio of 9:1 for primarily lowering cholesterol levels.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of multiple combinations of phyto-oestrogen in the treatment of conditions selected from the group consisting of breast cancer, benign breast disease, PMS and Symptoms associated with menopause and combinations. There is little guidance for treating "potential disease conditions" in females. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, of improvement in the health of a female who "might" develop one or a combination of the conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of two or more phyto-oestrogen compounds to treat female's with the conditions

instantly claimed.

3. WORKING EXAMPLES IN SPECIFICATION

The examples of the efficacy of the instant methods and the applicability of the active agents is set forth in the following examples:

Examples 1 and 2 are drawn to Methods for extracting phyto-oestrogen products from Red Clover and Soya Hypocotyl respectively. Example 3 is drawn to the administration of Red Clover products and the comparison of said clover products to legumes on blood cholesterol levels. Four individuals, 3 men and 1 woman were administered the Red Clover Extract. Example 4 is drawn to the administration of Soy Hypocotyl products and documented the effect on blood cholesterol levels.

The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breath of the claims for treating patients with conditions selected from the group consisting of breast cancer, benign breast disease, PMS, Symptoms associated with menopause, or combinations of said conditions (which includes treating two to all four conditions simultaneously).

4. NATURE OF THE INVENTION

It is known in this art that certain phyto-oestrogen compounds have efficacy in treating specific conditions diseases associated with oestrogen metabolism. The exact mechanisms of action and the effects of these phyto-oestrogen compounds may be found in columns

1, 2, 3, 4, 5 and 6 of U.S. Patent 5,516,528.

5. STATE OF THE PRIOR ART

The instantly claimed compositions and therapeutic methods are drawn to using phyto-oestrogen compositions for treating various conditions in humans. The following patents are cited to show the state of the prior art:

Hughes et al.	5,516,528	May 14, 1996
Zilliken	4,390,559	June 28, 1983
Zilliken	4,366,082	December 28, 1982
Zilliken	4,264,509	April 28, 1981

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from the class of compounds represented by the specific isoflavones daidzein and genistein, to include the methoxy substituted forms of said isoflavones is not seen to be disclosed in the prior art and is not seen how the skilled artisans would extrapolate such methoxy substituted forms of said compounds as a predictable indication of the ability of such substituted compounds to be efficacious as is instantly asserted. The specification nor the prior art provides adequate guidance for equivocating the isoflavones and their substituted derivatives in methods for treating conditions in humans. Further, to extrapolate data for the control of blood cholesterol levels to encompass the treatment of one or more conditions selected from breast cancer, benign breast disease, PMS and Symptoms associated

with Menopause is not seen to be conventional in the art of chemotherapy. The extrapolation is not seen to be based upon data which would adequately substantiate the treatment of the conditions cited supra in patients who "might develop" such conditions.

7. BREATH OF THE CLAIMS

Claims 1 is drawn to a health supplement which must contain at least two of the phyto-oestrogens selected from the group consisting of genistein, daidzein, biochanin A, formononectin or the glycosides of same. Claim 2 is drawn to a health supplement which includes an excipient, diluent, carrier or food. Claims 3-5 which depend from claim 1, are drawn to phyto-oestrogen components derived from red clover, soya[sic], and soya[sic] hypocotyls respectively. Claim 6 is drawn to a supplement comprised of a) genistein [optionally including biochanin A], and b) daidzein [optionally including formononectin] at a ratio range of 1:2 to 2:1. Claim 7 and 8 are drawn to specific dosages of the composition of claim 1. Claim 9 is drawn to tablet or capsule forms of the composition of claim 1. Claim 10 is an independent method claim drawn to improving the health of a human comprising administering any two or more of the potential compositions of claim 1. Claims 11-13, which depend from claim 10, are drawn to methods requiring the phyto-oestrogen components derived from red clover, soy and soy hypoctyls. Claim 14 which depends from claim 10, requires the method to employ the potential compositions of claim 6. Claims 15

and 16, which depend from method claim 10, are drawn to the use of specific dosages for administration. Claim 17 is drawn to the method of claim 10 wherein the administration is at least once a day and the treatment is continued for at least a month. Claim 18 which depends from claim 10 is drawn to improving the health of a human female 1) who has, or 2) may develop a condition selected from breast cancer, benign breast disease, pre-menstrual syndrome, symptoms associated with menopause, or a combination. Claims 19 and 20 depend from claim 10 and are drawn to treating a human who 1) has or 2) may develop elevated levels of cholesterol in the blood stream and cancer respectively. Claims 21 and 22 are drawn to tablet or capsule forms of the compositions of claims 6 and 7 respectively. Claim 23 which depends from claim 14, and claim 24 which depends from claim 15, are intended to specifically improve the health of a human female by administering the active agent of claim 14 in treating or potentially preventing the conditions of claim 18. Claims 25 and 27 which depend from claim 14, and claims 26 and 28 which depend from claim 15, are drawn to methods for treating elevated levels of cholesterol in the blood stream and cancer respectively.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to methods for formulating phyto-oestrogen compositions and treating or preventing the conditions as set forth in claim 18 is that of a PhD or MD

level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims which encompass treating healthy humans and females. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of the potential compositions for inclusion in a health supplement would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

Claims 1-28 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this

section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-9, 21 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over the Zilliken Patent 4,366,082.

Claims 1-9, 21 and 22 are all drawn to compositions which contain two or more phyto-oestrogen compounds, or their glycosides.

The Zilliken patent teaches that the class of compounds instantly claimed are recognized in the art as effective antioxidants, see column 2, lines 34-43. Applicant's attention is directed to column 5, lines 24-27, wherein one or more compounds of denoted by Compounds I, see column 3, lines 51-66 are intended to be included into compositions.

It would be obvious to one having ordinary skill in the art at the time the invention was made to include one or more phyto-oestrogen compounds into a composition to improve the health of the recipient because the prior art discloses the inclusion of this class of compounds generically into compositions to be used as antioxidants. The disclosure of these compounds in composition form render the instantly claimed compositions obvious because the motivation to combine same is clearly set forth in the disclosure of these phyto-oestrogen or isoflavone compounds as included in the antioxidant compositions of the prior art.

Any inquiry concerning this communication should be directed

to James O. Wilson, Primary Patent Examiner, Art Unit 1211 at telephone number (703) 308-4624.

JAMES O. WILSON
PATENT EXAMINER
GROUP 1200